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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/770,216	01/29/2001	Michel Schneider	1201-86	8806

7590 11/20/2002  
NIXON & VANDERHYE P.C.  
1100 North Glebe Road, 8th Floor  
Arlington, VA 22201

EXAMINER

SHARAREH, SHAHNAM J

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 11/20/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/770,216

Applicant(s)

SCHNEIDER ET AL.

Examiner

Shahnam Sharareh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 1/29/2001, 9/27/2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-60 is/are pending in the application.
- 4a) Of the above claim(s) 1-21 and 35-47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 22-34 and 48-60 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All   b) ☐ Some \*   c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. 07/134,671.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2, 10.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Applicant's election of Group II, claims 22-34, 48-60 in Paper No. 8 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 35-37 were inadvertently missed in the Election/Restriction requirement, which is hereby included into Group II.

Claims 1-21, 38-47, withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 8.

### ***Effective Priority Date***

Applicant is informed that in order to receive the benefit of an earlier filing Applicant must first convey the inventive concept of the claim as a whole consistent with the requirements of the USC § 112 first paragraph. Accordingly, the parent cases must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, that the inventor was in possession of the invention. MPEP 2163.05 (I). In the instant case, the claimed dry formulations wherein microbubbles comprise SF6 and the straight chain saturated fatty acid is arachidic, behenic or lignoceric acid, was not disclosed in the parent cases. Accordingly, the effective priority date of the instant application is January 29, 2001, because the invention as a whole was first disclosed at this date.

### ***Claim Rjections - 35 USC § 103***

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 22-34, 48-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beller et al US Patent 5,599,523 in view of Unger et al US Patent 5,542,935, Klaveness US Patent 5,529,766 and Quay US Patent 5,393,424.

Beller teaches echo contrast agent comprising a polymer, anionic phospholipid, and a gas (see abstract). Beller uses anionic phospholipids such as DPPG or DSPG in amounts of about 0.01 to about 5% (see col 1, lines 55-59). Beller's microbubbles does not contain palmitic acid. Further, Beller does not explicitly teach freeze dried formulations containing SF<sub>6</sub>.

Unger also teaches the use of fatty acids such as palmitic acid in preparing more stable microspheres. Unger also teaches that it is well understood by one skilled in the art that the lipids or liposomes may be manipulated prior and subsequent to being subjected to the methods of the present invention. For example, Unger states that the lipid may be hydrated and then lyophilized, or processed through freeze and thaw cycles, or simply hydrated prior to the formation of gaseous microspheres (col 40, lines 5-25). Finally, Unger teaches the use of Sulfur hexafluoride as a suitable gas (see col 67, lines 8-13).

Klaveness complement the teachings of Unger by providing the use of polymeric microbubbles that can contain sulfur hexafluoride (abstract, claims 1-10). Similarly, Quay indicates the advantages of using such gases that have a Q coefficient higher than 30 (col 10-14). Sulfur hexafluoride has a Q value of 722 (col 14, table II).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of invention to modify Beller's microbubbles and incorporate a fatty acid such as palmitic acid, as suggested by Unger, and then employ sulfur hexafluoride, as the gas of choice, because as suggested by Unger, and recommended by Klaveness and

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Quay, the ordinary artisan would have had a reasonable expectation of success in improving the utility of Beller's microbubbles in ultrasound imaging.

Furthermore, as suggested by Unger, methods of Freeze drying microbubble formulations is conventional in the art, and it would have been obvious to one of ordinary skill in the art at the time of invention to prepare a freeze dried formulation of Beller prior to use, because the ordinary artisan would have expected improved stability and ease of storage.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 22-34, 48-60 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 5,380,519 and claims 1-50 of US Patent 6,110,443. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to dry formulations comprising a phospholipid, a stabilizing polymer and gaseous microbubbles.

The patented claims differ as they do not explicitly teach the instant concentrations of phospholipids, however, it would have been obvious to one of ordinary skill in the art at the time of invention to optimize the phospholipid concentrations of the patented claims in order to practice the instant invention.

Claims 22-34, 48-60 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 37-48, 85 of copending Application No. 09/748,120. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are both directed to dry formulations of gaseous microbubbles comprising halogenated hydrocarbons and freons. Accordingly it would have been obvious to one of ordinary skill in the art at the time of invention to practice one when in possession of the other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 703-306-5400. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 703-308-1877. The fax phone numbers for the organization where this application or proceeding is assigned

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are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

ss  
November 18, 2002

  
RUSSELL TRAVERS  
PRIMARY EXAMINER  
GROUP 1200